PART VI
DIALYSIS & HAEMOPERFUSION
Chairmen: H Klinkmann
V Parsons
Wrist Watch-size Single Needle Clamping Device

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Summary

In this paper the need for the single needle system (SND) of haemodialysis is explained. The disadvantages of currently available systems are described. An improved system has been developed at the Royal Free Hospital. Stages in its development have been described. It is concluded that although the new Royal Free Hospital SND offers a reduction in recirculation and allows a faster blood flow, it does not achieve the dialysance of a two needle dialysis under similar circumstances. Other adjuncts such as more frequent dialysis and/or larger surface area dialysers are needed if single needle dialysis is to be used routinely.

Introduction

Recent technical advances in haemodialysis have attempted to reduce drastically the length of time on dialysis by increasing the efficiency and frequency of dialysis. Since the standard method of access to the blood stream is venepuncture of an arteriovenous fistula, the increased frequency of needling may reduce fistula survival. In addition, the physical and mental trauma of insertion of needles may make more frequent dialysis unacceptable. This is particularly relevant to children. Certain patients, especially the old, may have limited lengths of suitable vessels for venepuncture. Consideration of these points emphasises the urgent need to develop a really efficient single needle system (SND).

Our initial experience with single needle systems showed them to be rather crude with several obvious problems. Some 'dead space' between the point of the needle and the division of the Y junction to the arterial and venous lines is inevitable. By selection of a very short junction this can be minimised, but the
dead space can be exaggerated by recirculation of blood from the venous to the arterial line. The extent of recirculation would depend on the timing and position of the clamps. In addition, negative pressure induced by the blood pumping from a closed clamp would allow collapse of standard blood lines and would encourage even more recirculation during the change-over time (Kopp et al, 1972, 1974). Stiff lines can be used, but this creates an even higher negative pressure allowing air to be sucked in if the lines are faulty. The position of the blood pump must be considered. For example, would it be better before or after the kidney, and should it be used as one of the clamps by stop/start technique? It is difficult to stop and start a mechanical object without loss of time and therefore efficiency. Many of the single needle systems use heavy powerful clamps which crush tubing, distorting the tubing and causing it to fail to re-open fully after the clamp is released. All the above points had greater significance when we considered our own needs in relation to the safety of home dialysis and in particular efficient home dialysis in children.

At the Royal Free Hospital we defined our requirements for a SND as follows: clamping at the site of the needle, therefore the clamping device had to be small and flexible enough to be strapped as a ‘wrist watch’ to the fistula arm. Clamping had to be swift but gentle, with momentary delay between exchange of clamping, to prevent recirculation, and finally it had to provide variable timing. The most suitable material for swift gentle clamping, but providing adequate blood flows, was silastic tubing of the diameter used in standard external shunts and which was commercially available for use by the SND after attachment to standard or double entry needles.

DEVELOPMENT

The project commenced in February 1974 and by April 1974 a hydraulic system was constructed consisting of a perspex block housing a rocking clamp with a spring biased in one position and operated to open and close the other side by expansion of a PVC sac filled with water. Operation of the hydraulic pressure was by a variable controlled pump head. Although this functioned, it allowed recirculation during the change from one position to another.

It became obvious that to overcome recirculation the clamps had to operate quickly but independently for maximum efficiency. The hydraulic system was abandoned as the viscosity of the fluid did not allow swift enough action. Direct clamping with solenoids was discounted for two reasons: firstly it brought the patient into direct contact with electricity, and secondly its size would have proved prohibitive. It was then decided to house, in a separate box, solenoids which could operate rocking clamps remotely via cables (Figure 1). This allowed the clamp head to be of a wearable size and weight. Operation of the solenoids, cables and thus the remote clamps is via a twin timer which allows independent control of each clamp on a 0–6 second time scale. The clamps operate on change-
over when both clamps are closed for a period of 0.1 seconds thus preventing recirculation. Two windows sited over the tubes in the clamp head allow visual indication of correct clamping (Figure 1). Since cable transmission is reduced if the cables are over-kinked, the siting of the clamp head on the patient's arm and the box housing the solenoids must allow the cables to be reasonably straight.

The initial prototypes of this model have been in use since April 1975 and have been used routinely at home by six children and two adults. In the hospital, two other prototypes have been used regularly on different patients. More recently a production model has been made available and has been used by a further fifteen patients in the home and three patients in the hospital.

Methods for Testing Technical Performance

Various tests to check recirculation and comparative efficiency of the Royal Free SND against two needle systems and a standard Gambro SND were undertaken. Four patients were dialysed using Dylade Model D3 and 1 m² Kiil dialysers. Each patient had two double entry needles placed at different levels in the fistula arm, one or both needles being suitable for single needle dialysis. A third needle for blood sampling was placed in the non-fistula arm. Each dialysis was started using two needle technique. Two different pump settings were selected for each patient; the maximum speed which did not cause a negative arterial pressure and a slower speed to allow for a venous pressure of 100 mmHg or less. Crude but consistently reproducible blood flow rates were measured by timing a bubble over a two metre length of arterial blood line; this being the only suit-
able method of measuring a stop-start flow. The blood flow rate was measured at the selected blood pump settings, firstly for two needle dialysis and then for a series of single needle dialyses with variable times for opening arterial (A) and venous (V) clamps. Blood samples were taken simultaneously from the fistula arterial line just before entry to the dialyser and from the venous line immediately after the bubble catcher, and from the non-fistula arm. A sample of out-flow dialysate was taken at the same time. These blood and dialysate samples were taken under the following running conditions: (1) two needle dialysis with variable blood flow rates; (2) Royal Free SND with variable blood flow rates and different needle sites; (3) Gambro SND with variable blood flow rates, different needle sites and near and far clamping sites. The plasma was separated from the blood and the red cells returned to the patient. Urea and creatinine were measured on the plasma and dialysate samples, and the results used to calculate dialysance and recirculation.

RESULTS

Comparing blood flow rates of two needles, Royal Free SND and Gambro SND, there was some reduction of blood flow using SNDS at slower pump speeds.

![Figure 2. Blood flow rates in ml/min at different pump settings](image-url)
(Figure 2), that with the Royal Free SND being slightly less than with the Gambro SND, but at high blood pump speeds, there was considerable decrease of flow rates when using either single needle system. Using the Royal Free SND the best flow rates were achieved with the arterial clamp open three seconds and the venous clamp only two seconds as indicated in Table I. Lengthening the time

<table>
<thead>
<tr>
<th>Pump Setting</th>
<th>A open</th>
<th>V open</th>
<th>Blood Flow Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1 350</td>
<td>2</td>
<td>2</td>
<td>140</td>
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<td></td>
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<td>130</td>
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<td>138</td>
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<td></td>
<td>*3</td>
<td>2</td>
<td>170*</td>
</tr>
<tr>
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<td>3</td>
<td>4</td>
<td>122</td>
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<td>171</td>
</tr>
<tr>
<td></td>
<td>*3</td>
<td>2</td>
<td>192*</td>
</tr>
<tr>
<td>P11 400</td>
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<td>2</td>
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<tr>
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<td>*3</td>
<td>2</td>
<td>255*</td>
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<tr>
<td></td>
<td>*3</td>
<td>2</td>
<td>280*</td>
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intervals did not increase the flow rates and made the venous pressure rise to unacceptable levels. Dialysance, as expected, was directly related to blood flow but varied slightly with individual patients. The average recirculation in ml per minute for two needles was 1.5 ml, compared with Royal Free SND 1.9 ml, Gambro SND sited as near as possible to the patient 3.2 ml, and Gambro SND distant from the patient, 10.8 ml.

**Clinical Experience**

The Royal Free SND used by six children and two adults in the home over the past year proved satisfactory, once the patient realised the necessity to keep the cables reasonably straight. Setting the low venous alarm close to the low swing of the venous bubble catcher pressure detected any failure of the clamping device.
Straightening of the cables usually rectified the fault. Further clinical testing of the Royal Free SND equipment was undertaken by asking fifteen stable experienced home patients to undertake a five week trial of the SND. The patients were asked not to change their dialysis technique, routine schedule or general habits of diet, etc. The SND was used every alternate dialysis instead of two needles. Each
patient sent in pre- and post-dialysis plasma samples from every dialysis. Four patients defaulted, three because they did not like their arm being restricted in any way, and one because he developed other medical problems. The results of the mean of the pre- and post-dialysis ureas and creatinines for single and two needle dialysis are shown in the scatter graph (Figure 3). Although there is no significant difference between the mean post dialysis ureas and creatinines, at the dialysis following a single needle dialysis, the pre dialysis urea and creatinine showed a clinically small but statistically significantly higher level than those after a two needle dialysis. After two-needle dialyses, the mean pre-dialysis urea was 149.8 mg/100 ml, SEM 11.3 while after single needle dialyses, the mean pre-dialysis urea was 169.3 mg/100 ml, SEM 13.4 (P<0.02). Corresponding values for creatinine were 13.0 mg/100 ml, SEM 0.5 and 14.1 mg/100 ml, SEM 0.7 respectively (P<0.01). This is confirmed by the finding of a statistically significant difference between the mean urea and creatinine fall during a single and double needle dialysis.

The patients liked the single needle dialysis because of the single puncture and feeling that their fistula arm benefited. Two did not feel as well as with two needles. Two complained of loss of independence because excessive movement of the arm was not allowed and after insertion of the needle they needed help to fit the lines in the clamp head.

Suggested improvements which are now being studied are monitoring to check clamping efficiency and the development of negative pressure at the needle site, to allow safer unobserved overnight dialysis. A more flexible but positive cable system is needed to give free movement of the fistula arm, and some modification of the clamping head will allow easier self-placement of lines and strapping to the arm.

CONCLUSION

At the Royal Free Hospital we feel that we have produced an alternative SND with improved features to prevent recirculation and increased speed of change-over of clamps, both of which improve the efficiency of single needle dialysis. However, our figures confirm that it is not as efficient as a two needle dialysis performed under similar conditions. Other factors, such as increased frequency of dialysis and more efficient dialysers are needed for its routine use.

References

Kopp, KF, Gutch, CF and Kolff, WJ (1972) Transactions American Society for Artificial Internal Organs, 8, 75
Open Discussion

KERR (Newcastle) Did you compare single and double needle dialysis at the maximum blood flow available from the fistula? It seems unfair to compare them under any other circumstances. And a second question. Does the difference in recirculation you demonstrated between your device and the commercially available ones make a significant difference to dialysis?

BAILLOD To the first question, I did not. When I was comparing the difference between the single and the two-needle, I did not change the system in any way. We left it as it was and just compared them directly. Obviously we can improve performances by increasing the pump speed, but we were just comparing them under the set conditions to see whether there were quite definite differences, and this we did show, although the differences are not very great. I think the recirculation does count, and I think we can improve on this. We have not as yet got the maximum efficiency out of our system.

KOPP (Munich) I think this was a very fine contribution to the problem of single needle dialysis and you have clearly pointed to the problems which we still encounter, but I think most of these problems are not so much with the hardware of single needle dialysis — although there are problems — but with the general attitude of not really going into the problems, and really examining them carefully enough. This does not apply to you! I think if one takes one of the available pieces of hardware one can really get very efficient single needle dialysis and this is our experience now over six years. One thing which I would like to point out is the over-emphasis on recirculation — that is, the question of reduction in efficiency. In our experience the hardware-induced recirculation does not play as big a role as is usually stated, and this may be one criticism of your paper. Admittedly, recirculation increases, as you have shown very nicely, when you have high negative pressure in the arterial line. This is the result, not of the hardware nor the needle, but probably of insufficient flow in the fistula. Where there is no blood flow you cannot draw any blood! Recirculation, however, does play a role if there is a big aneurysm and pooling of blood, and if there is no run-off of blood. This has to be corrected surgically. Unfortunately in just such conditions single needle dialysis is used because of the problems of blood access. So I would caution a little bit against over-emphasis on recirculation, because even with the available hardware, recirculation in properly conducted single needle dialysis does not play much of a role in reducing the efficiency of dialysis.

CHAIRMAN Thank you very much for this comment. Would you like to reply?

BAILLOD No.